REMARKS

Applicants request reconsideration of the application in view of the Amendments to the claims and the remarks presented herein.

The claims in the application are claims 1, 3 and 5 to 18. All other claims having been cancelled.

Claims 1, 3, 5 to 8, 11, 12, 14, 15 and 18 have been rejected under 35 USC 103 as being obvious over the Saunal et al reference and Maillo et al '211 taken in view of the Winters '409 reference. Claims 9, 10, 13, 16 and 17 have been rejected under 35 USC 103 as being obvious over the same prior art taken in further view of the Merck Index, the Eibl et al patent and Remington's Pharmaceutical Sciences reference. The Examiner states that the Saunal et al reference teaches a transdermal topical formulation using a solvent and absorption promoting agent, an active steroid and a film-forming agent while Winters et al allegedly teaches a topical formulation of 19-nor progesterone for systemic delivery of the active ingredient having a solvent film-forming agent and cellulose in a plasticizing agent. The Examiner concedes that the primary references do not teach the use of preferred carrier materials of propyleneglycol and the like and that they do not teach the weight ratio of nomegesterol to be 0.05 to 1% by weight and do not teach the specific ratios.

The Examiner cites the Eibl et al patent as teaching propyleneglycol and copolymers of methacrylic acid and ethyl acrylate as being an auxiliary agent for pharmaceuticals and topical formulations. The Merck Index is cited to show that isopropylpropylidene glycerol my be used as a plasticizing agent and the Remington Sciences reference is cited to show that carbomer is useful as a gelling and emulsifying agent and therefore, deems that the claimed compositions would be obvious.

Applicants respectfully traverse these grounds of rejection since the combination of the prior art that the Examiner has made with the benefit of Applicants' disclosure would not suggest Applicants' invention to one skilled in the art, particularly since there is no suggestion or teaching to combine the references as the Examiner has done with the benefit of Applicants' disclosure. The Saunal et al patent relates to compositions for transdermal delivery of an active ingredient which could possibly be nomegesterol acetate and optionally a polymeric release matrix capable of forming a flexible film when dried which matrix is selected from the group consisting of cellulose polymers or copolymers, vinyl- pyrrolidene, vinyl acetate copolymers and a physiologically non-aqueous solvent to dissolve the release matrix and the transcutaneous absorption promoter by quickly removing the same by evaporation from the skin.

Transdermal compositions are completely different from a gel with systemic activity. Transdermal compositions are made of a small reservoir fixed to a strip of plastic material and the reservoir is then placed against the skin. The reservoir normally contains a large amount of an active ingredient dissolved in a lipophilic diluent and the

active ingredient diffuses through the skin from the lipophilic phase. The objective of such a preparation is to have a delayed or protracted diffusion of the active ingredient through the skin and a transdermal device is not intended to have the product reach the bloodstream as in Applicants' composition but is intended to diffuse the active ingredient from the reservoir through the skin. The compounds present in the reservoir are selected due to their high lipophilicity and includes compounds such as estradiol, scopolamine, nicotine and the like.

Applicants formulation, as noted above, has absolutely nothing to do with a transdermal application since Applicants' invention is intended to ensure passage of the active ingredient nomegesterol acetate into the bloodstream and therefore, the Saunal et al patent in no way relates to Applicants' invention.

The Maillos et al reference relates to 19-nor pregnane derivatives which are potent progestogens devoid of residual androgenic activity. The reference teaches oral administration but also parental administration, intramuscular subcutaneous and percutaneous and vaginal, ocular or nasal roots in the form of solid, semi-solid or liquid dosage form and refers to all pharmaceutical compositions generally but does not teach Applicants' compositions.

The Winters et al reference does not overcome the deficiencies of the primary references as it is directed to a topical polymeric drug delivery system to deliver drugs to the skin topically by the use of a propellant free airless pump for the deliver which has absolutely nothing to do with Applicants' invention. The tertiary references do not

overcome the deficiencies of the primary and secondary references and one skilled in the art would not combine the same to obtain Applicants' novel compositions with their novel activity.

Synthetic progesterones have the main drawback of having very poor diffusion properties through the skin due to their lipophilic character and Applicants' invention provides a precise balance between the solubility of the active ingredient and the vehicle and its ability to diffuse through the skin towards the bloodstream. This is why the mixture proportion of the preferred solubilizing agent suitable for Applicants' invetnion is the main point of distinction with respect to the prior art. The effectiveness of the composition is the result of the proper combination and term of dosage of all the excipients.

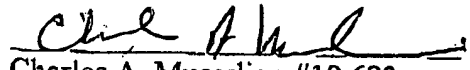
In Applicants' invention, the preferred solubilizing agent is a ternary mixture or a quaternary mixture of 95% ethanol/water/propyleneglycol and optionally Labrasol wherein the percentage of 95% ethanol varies from 30 to 50% and the amount of water is 30 to 60% and the propyleneglycol is 2 to 20% and the Labrasol is 3 to 7%, all percentages being by weight. This composition permits nomegesterol to pass through the cutaneous barrier to obtain good clinical results when the excipient mixture proportions are properly balanced as can be seen from the examples in the application as filed.

The Saunal et al compositions do not contain propylene glycol which contributes to the effectiveness of the diffusion through the skin and Saunal et al did not show any

examples of compositions containing 19-nor progesterone derivatives and specifically not nomegesterol acetate. The reference taught estradiol compositions as being easily obtained and satisfactorily efficient due to the high lipophilicity of estradiol. Saunal et al only postulates the possibility that these compositions could contain nomegesterol acetate and does not teach Applicants' advantages of the compositions. There is no way to obtain Applicants' gel having systemic activity with the active ingredients being highly lipophlic. Therefore, withdrawal of these grounds of rejection is requested.

In view of the amendment to the claims and the above remarks, it is believed that the claims point out Applicants' invention and favorable reconsideration of the application is requested.

Respectfully submitted,
Hedman and Costigan



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Enclosures

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